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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,014	AKIMOTO ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 6, 8 - 35* is/are pending in the application.

4a) Of the above claim(s) *20 - 31, 33 - 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 6, 8 - 19, 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/26/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed January 5, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 – 6, 8 – 12 and 32 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 21 and 31 of copending Application No. 10/485,456 in view of Willatts et al. (Lancet 1998). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds the claims of '456 do not recite that the method "prevents decline of, improves or enhances cognitive ability responses of a healthy person", on which Willatts et al. is improperly relied upon for that suggestion. Problem solving ability in infants, as taught by Willatts et al., is not as cognitive ability as defined in the specification of the instant application. The claims of the copending application have not been allowed and could be amended, which may render the claim unobvious for further reasons.

These arguments are not found to be persuasive. The preamble reciting the effect of the method between the two applications are not identical. However, the active steps of the method are the same, administering a composition comprising arachidonic acid (AA) and/or a compound with arachidonic acid as a constituent fatty acid. Therefore, the effects of the method must be the same. The instant claims have been amended to “an amount sufficient to prevent decline of, improve or enhance cognitive ability responses of a healthy person". Later claims, such as claims 6 and 7, recite the same actual amounts of AA. Willatts et al. discloses absolute amounts of arachidonic acid that is effective for one particular aspect of cognitive ability responses. A limited definition of “cognitive ability responses” is not given by Applicant as the definition given concludes with “and the like” (p 2, ln 11) and therefore improved problem solving speed is not excluded. This rejection is MAINTAINED.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 13 – 19 and 32 were rejected under 35 U.S.C. 102(b) as being anticipated by Willatts et al. (Lancet 1998). This rejection is MAINTAINED for the

reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Willatts fails to explicitly or implicitly disclose the limitation "in an amount sufficient to prevent decline of, improve or enhance cognitive ability responses of a healthy person". Higher percentages of AA compared to other fatty acids are needed to meet this limitation as shown at p 13, ln 9-14 of the instant specification. Problem solving is not included in the definition of cognitive abilities in the present application.

These arguments are not found to be persuasive. Willatts et al. discloses a composition with an amount of AA that is sufficient to improve problem solving skills. A limited definition of "cognitive ability responses" is not given by Applicant as the definition given concludes with "and the like" (p 2, ln 11) and therefore improved problem solving speed is not excluded. The specification of the instant application recites that "a higher proportion of arachidonic acid is preferred with respect to the total fatty acids in arachidonic acid-containing oils or fats (p 13, ln 9 – 12, emphasis added) and the claims do not require a higher proportion of AA. Therefore, effective amounts AA can encompass compositions in which arachidonic acid is present in a lower proportion in regards to the total fatty acids. Problem solving ability, with elements of memory (what is under the covering) and perception, is not excluded by the instant claims and therefore all of the claimed limitations are met.

5. Claims 1, 2 and 13 – 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kiliaan et al. (US 2002/0040058). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below, although it is no longer applied to amended claim 6 and its dependent claim 8.

Applicant traverses this rejection on the grounds that Kiliaan et al. fails to explicitly or implicitly disclose the limitation "in an amount sufficient to prevent decline of, improve or enhance cognitive ability responses of a healthy person". Killian et al. discloses a method for the prevention and/or treatment of vascular disorders and/or secondary disorders associated therewith. Kiliaan et al. requires a high ratio of DHA and EPA to AA and DHGLA, whereas higher percentages of AA compared to other fatty acids are needed to prevent decline of, improve or enhance cognitive ability responses of a healthy person.

These arguments are not found to be persuasive. Applicant have clarified that the "healthy" subjects to be treated using this method are healthy in regards to their cognitive ability health (p 10, ¶ 2). There is no indication in Kiliaan et al. that these patients have unhealthy cognitive ability responses. The specification of the instant application recites that "a higher proportion of arachidonic acid is preferred with respect to the total fatty acids in arachidonic acid-containing oils or fats (p 13, ln 9 – 12, emphasis added) and the claims do not require the higher proportion of AA. Therefore, effective amounts AA can encompass compositions in which arachidonic acid is present in a lower proportion in regards to the total fatty acids. Both Kiliaan et al. and the instant claims recite the administration of a composition comprising arachidonic acid. Applicant

had indicated a daily intake of 0.001 – 20 g, 0.01 – 10 g, 0.05 – 5 g and most preferably 0.1 – 2 g. The preparations of Kiliaan et al. comprise at least 50 mg, more preferably 100 mg (¶ [0066]). These amounts anticipated the ranges presented by Applicant is the specification as dosages within the scope of the invention and therefore represent "an amount sufficient to prevent decline of, improve or enhance cognitive ability responses of a healthy person."

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2, 6, 8, 9, 13 – 19 and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Willatts et al. in view of Barclay (US 5,583,019). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below.

Applicants traverse this rejection on the grounds that Willatts et al. fails to disclose the limitation "in an amount sufficient to prevent decline of, improve or enhance cognitive ability responses of a healthy person" as discussed above. The Office provided no clear articulation why it would be obvious to provide infant formula of Willatts et al. with higher concentration of AA or to substitute the infant formula of Barclay with higher concentrations of AA. Barclay does not teach that the compositions with higher concentrations of AA improve cognitive ability responses of healthy person or even problem solving. Barclay is concerned with cellular metabolism and growth in infants and the modifications proposed by the Office would render Willatts et al. unsatisfactory for its intended purpose. Willatts et al. states that changes in the amounts of long-chain unsaturated fatty acids can have dramatic changes to problems solving and that changing the fatty acid composition of Willatts to include a much larger

concentration of AA would render Willatts et al. unsatisfactory for the purpose of improving problem solving. Barclay uses triglycerides to provide AA but no suggestion is articulated for why it is obvious to modify Willatts to use the triglyceride of Barclay and there is no motivation or expectation success to use a completely different fatty acid composition having an AA concentration increased from 0.4 wt% to at least 10 wt%.

These arguments are not persuasive. The Examiner is unsure to what particular passage on p 688 Applicant is referring to in regards to the statement “changes in the amounts of long-chain unsaturated fatty acids can have dramatic changes to problems solving”. A more precise citation with column and paragraph/line number rather than the page number only for this idea is requested. The closest passage the Examiner could locate on this page in the “interpretation" segment of the summary and the last paragraph of column 2, both of which indicate that the presence of LCPUFA supplementation resulted in the higher problem solving skills observed in infants. So while there is a relatively large change in going from no supplementation to the supplementation put forth, the Examiner was unable to locate any statement which indicated higher amounts of AA would result in either no increase or even a decrease in problem solving skills. Therefore, the Examiner is not persuaded that increasing the concentration of AA in the compositions of Willatts et al. would render it unsatisfactory for its intended purpose.

Barclay is concerned with ways in which a particular ingredient may be made and provided in food products to enhance the AA content of the food product. It is unclear why one would not have an expectation of success in providing the AA as a constituent

fatty acid as Barclay teaches that such a material can be used in infant formula, the same specific ingredient and application as that as in Willatts et al. in order to enhance the AA content of the food product (abstract).

10. Claims 1 – 6, 8 – 19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willatts and Barclay further in view of JP 08-214891 (JP '891). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below.

Applicant traverses this rejection on the additional grounds that discussed above in regards to Willatts et al. and Barclay. JP '891 cannot be combined to cure these deficiencies as it does not suggest adding AA in amounts that would provide for the limitation of "preventing decline of, improving or enhancing cognitive ability responses of a healthy person" and that the Office has misconstrued JP '891 as stating that JP '891 teaches an AA content of about 30%. The paragraph 27 cited by the Office has a particular example in which the concentration of DHA is about 30%. In the examples, AA is present in amounts less than 3wt%. JP '891 does not suggest using triglycerides wherein the AA concentration is 10wt% or more relative to all the fatty acids and "at least 5 mole percent of triglycerides with medium-chain fatty acids bound at the 1,3 positions and AA bound at the 2-position". There is no motivation or expectation of success that higher amounts will provided different results.

These arguments are not found to be persuasive. Willatts et al. and Barclay do teach effective amounts as discussed in greater detail in the previous section. The

Examiner has indicated that DHA is present at the 2-position at a concentration with medium chain fatty acids present at the 1 and 3 positions on the sentence bridging p 11 and 12 of the previous Office Action. It is further explained that this reference teaches higher unsaturated fatty acids, of which AA is also given as an example, at the 2-position of the triglyceride. The materials of JP '891 provide a large amount of these fatty acids (condensed to high concentration; ¶¶ [0004] – [0005]). The use of the triglycerides of JP'891 as the source of the AA used in the method taught by McGahon et al. and Willatts et al. would result in a composition in which 100 mole percent of the triglycerides would have medium-chain fatty acids bound at the 1,3-positions and AA bound at the 2-position. The Examiner disagrees with Applicants' statement that there is no expectation of success in using higher amounts of an active ingredient to achieve different results. One of ordinary skill in the art would expect that higher doses of the active ingredient will have larger effects. Because of toxicity and other concerns regarding side effects, however, the minimal effective dose is generally used but one of ordinary skill in the art would routinely optimize the dose of the active ingredient in order to achieve the optimal therapeutic effect while minimizing side effects and toxicity of the active ingredient.

11. Claims 1, 13 – 19 and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over McGahon et al. (Neuroscience 1997) in view of Willatts et al. (Lancet 1998). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that long term potentiation is not included in the definition of cognitive abilities defined above. McGahon teaches that impaired performance in spatial learning tasks results from impaired ability to sustain long-term potentiation. Willatts et al. does not cure the deficiency of disclosing a method of preventing decline of, improving or enhancing cognitive ability responses of a healthy person.

These arguments are not found to be persuasive. Long term potentiation is a measure of the strength of communication between neurons, and strong neuronal connections are required for cognitive abilities. As discussed above, Applicants have not provided a limited definition of cognitive ability responses so improved long term potentiation is not excluded. The amounts of AA provided are sufficient to prevent the decline of, improve or enhance the cognitive ability response of a healthy person.

12. Claims 1 – 6, 8 – 19 and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over McGahon et al. and Willatts et al. further in view of JP 08-214891 (JP '891). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that in addition to the arguments presented above, JP '891 cannot be combined to cure these deficiencies as it does not suggest adding AA in amounts that would provide for the limitation of "preventing decline of, improving or enhancing cognitive ability responses of a healthy person" and that the Office has misconstrued JP '891 as stating that JP '891 teaches an AA content

of about 30%. The paragraph 27 cited by the Office has a particular example in which the concentration of DHA is about 30%. In the examples, AA is present in amounts less than 3wt%. JP '891 does not suggest using triglycerides wherein the AA concentration is 10wt% or more relative to all the fatty acids and "at least 5 mole percent of triglycerides with medium-chain fatty acids bound at the 1,3 positions and AA bound at the 2-position". There is no motivation or expectation of success that higher amounts will provided different results.

These arguments are not found to be persuasive. McGahon et al. and Willatts et al. do teach effective amounts as discussed in greater detail in the previous section. The Examiner has indicated that DHA is present at the 2-position at a concentration with medium chain fatty acids present at the 1 and 3 positions on the sentence bridging p 11 and 12 of the previous Office Action. It is further explained that this reference teaches higher unsaturated fatty acids, of which AA is also given as an example, at the 2-position of the triglyceride. The materials of JP '891 provide large amounts of these fatty acids (condensed to high concentration; ¶¶ [0004] – [0005]). The use of the triglycerides of JP'891 as the source of the AA used in the method taught by McGahon et al. and Willatts et al. would result in a composition in which 100 mole percent of the triglycerides would have medium-chain fatty acids bound at the 1,3-positions and AA bound at the 2-position. The Examiner disagrees with Applicants' statement that there is no expectation of success in using higher amounts of an active ingredient to achieve different results. One of ordinary skill in the art would expect that higher doses of the active ingredient will have larger effects. Because of toxicity and other concerns

regarding side effects, however, the minimal effective dose is generally used but one of ordinary skill in the art would routinely optimize the dose of the active ingredient in order to achieve the optimal therapeutic effect while minimizing side effects and toxicity of the active ingredient.

13. Claims 1, 2 and 13 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan in view of Barclay. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below.

Applicant traverses this rejection on the grounds regarding Kiliaan as discussed above in which the compositions contain an excess of EPA over AA. Elimination of the EPA from the fatty acid composition would render the composition unsuitable for its intended purpose. Therefore Kiliaan teaches away from eliminating the EPA and increasing the AA concentration in the composition and therefore the teachings of Barclay and Kiliaan cannot be combined.

These arguments are not persuasive. Neither Barclay nor the instant claims require that EPA be excluded from the composition. Therefore, the combination of Kiliaan and Barclay does not require the elimination of EPA from the composition and therefore the composition of Kiliaan is not rendered unsuitable for its intended purpose. The compositions of Kiliaan in which there is an excess of EPA over AA are not excluded by the instant claims.

14. Claims 1 – 6 and 8 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan in view of JP '891. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed July 3, 2008 and those set forth below.

Applicant traverse this rejection on the grounds that JP '891 does not suggest using triglycerides wherein the AA concentration should be sufficient to prevent decline of, improve or enhancing cognitive ability responses in a healthy person and "at least 5 mole percent of triglycerides with medium-chain fatty acids bound at the 1,3 positions and AA bound at the 2-position". There is no motivation or expectation of success that higher amounts will provided different results.

These arguments are not found to be persuasive. Kiliaan et al. does teach effective amounts, as discussed in greater above. The materials of JP '891 provide large amounts of these fatty acids (condensed to high concentration; ¶¶ [0004] – [0005]). The use of the triglycerides of JP'891 as the source of the AA used in the method taught by Kiliaan et would result in a composition in which 100 mole percent of the triglycerides would have medium-chain fatty acids bound at the 1,3-positions and AA bound at the 2-position.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW